K012837

SEP 1 4 2001

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Cardiocap 5 (Rev B) and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:
Mr. Joel Kent

DATE:
August 18, 2001

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda Cardiocap 5 (Rev B) and accessories

COMMON NAME:

Patient Monitor and accessories

CLASSIFICATION NAME:

The following Class III classification appears applicable:

Monitor, ST-segment with alarm 870.1025

The following Class II classifications appear applicable:

Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	868.1400
Transducer signal amplifier and conditioner	870.2060
Oximeter	870.2700
Ear Oximeter	870.2710
Cardiac Monitor	870.2300
Electrocardiographic Device	870.2340
Non-invasive blood pressure measurement sys.	870.1130
Stimulator, nerve, peripheral, electric	868.2775
Analyzer gas, Halothane, gaseous phase	868.1620

Analyzer gas, Nitrous oxide, gaseous phase	868.1700
Analyzer gas, Oxygen, gaseous phase	868.1720
Spirometer , monitoring, w/wo alarm	868.1850
Clinical Electronic Thermometer	880.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda Cardiocap 5 Rev B and accessories is substantially equivalent) in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Cardiocap 5 Rev A (K992323).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Cardiocap 5 monitor is a multi-parameter monitor that is factory configured. The monitor provides basic hemodynamic monitoring of ECG, SpO2, Temp, NIBP and Invasive pressures. In addition to the hemodynamic monitoring it can be configured with Gas monitoring which are: CO2, N2O, O2, Anesthetic Agents with agent identification and Patient Spirometry TM .

The Cardiocap 5 monitor software available is for Anesthesia or Critical Care. The customer upon purchase for optimized use of monitor can select the software for application.

In addition the Cardiocap 5 rev. B will offer other options and enhanced features. These features are the following:

OSAT – Enhanced D-O Oximetry (SpO2) performance
NSAT – Nellcor Oximetry
XP w/2 temp – Invasive pressure with 2 temp feature
Rec. w/2 key – Recorder with 2 direct key function

Because the Cardiocap 5 monitor is factory-configured for cost-effectiveness and compactness, the parameters and optional thermal array recorder cannot be upgraded later. Software is upgradeable.

Cardiocap 5 is based on the same state-of-the-art monitoring and user interface technology, including menu logic and alarm philosophy, as the S/5 monitors. The Cardiocap 5 can also be networked to the Datex-Ohmeda Network.

The hemodynamic frame (F-MX) and hemodynamic with gases frame (F-MXG) both include ECG with ST analysis and impedance respiration, SpO2, 1 temperature, and non-invasive blood pressure. Invasive blood pressures (2 channels) and second temperature is an option for both models. Airway gas options are for hemodynamic with gases frame .

The Cardiocap 5 monitor now extends its feature sets to allow flexibility of customer-preferred oximetry options. These new oximetry features replace the functionality of the original oximetry offering. (Only one oximetry option is available at a time.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda Cardiocap/5□ is intended for use as part of the Datex-Ohmeda family of multi-parameter patient monitors. It is available with a set of factory-configured options, two different monitor software options and accessories.

The Datex-Ohmeda Cardiocap 5 (REV. B) and accessories are indicated for indoor monitoring of hemodynamic (ECG, Impedance respiration, NIBP, Temperature, SPO2 and invasive pressure) , respiratory (CO2, O2, N2O, respiration rate, anesthetic agent and agent identification), ventilatory (airway pressure, volume and flow) and relaxation status (NMT) of all hospital patients.
With the N-XOSAT option, monitoring of arterial oxygen saturation includes monitoring hospital patients under clinical motion conditions.
Impedance Respiration measurement is indicated for patients ages 3 years and older.
Cardiocap/5 is indicated for patients weighing 5 kg (11 lb.) or more.
The monitor is indicated for use by qualified medical personnel only

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Cardiocap 5 Rev B is substantially equivalent to Datex-Ohmeda Cardiocap 5 Rev A (K992323). The intended use of the devices have not changed. The indications for use for Cardiocap 5 REV B. and the predicate is nearly identical. Information about the N-XOSAT monitoring SPO2 during clinical motion conditions was added.

The software was updated to incorporate those changes noted below but otherwise is the same as the predicate. The hardware is essentially the same with the exception of adding a new quick pushbutton key for simpler access to the recorder trend function.

□ Various feature improvement updates, and requests by customers, manufacturing, and service on minor (non-safety) related changes.

□ A change from Cardiocap Rev. A to the subsequent version A+ (current production version) is related to the Datex-Ohmeda Cardiocap/5 software S-XANE99 rev.01 and S-XCCA99 rev.01 There were no hardware changes involved. This software change makes the Datex-Ohmeda Cardiocap/5 (Models F-MX, F-MXG) and accessories compatible with the Datex-Ohmeda CS/3 Arrhythmia Workstation (K974747) equipped with software S-ARR99 (K974747).

□ The Cardiocap 5 REV. B measurement of ECG, SpO2, Temperature, invasive and non-invasive blood pressures together with respiration, CO2, O2, N2O, Anesthetic Agents and Agent ID, Patient Spirometry™, NMT, recorder and datacard/network functionality are all identical to the predicate Cardiocap/5 Rev A (see attached table). The Cardiocap 5 REV. B and predicate use almost all the same accessories.

□ The only paramater differences are to add a 2nd temperature option (specification is the same as predicate) and to add options for two additional SPO2 measurement options N-XNSAT (Nellcor oximetry) and N-XOSAT (D-O enhanced oximetry).

In summary, it is evident that the main features and indications for use are substantially equivalent with the predicate Cardiocap/5 Rev A device (K992323). The comparisons above as well as supporting data and analysis shows that there are no new questions of

safety and effectiveness for the Cardiocap/5 Rev B and accessories described in this submission is substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda Cardiocap 5 (REV. B) and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 601-1 (1988) + Amendment 1 (1991) + Amendment 2 (1995)
- EN 60601-1 (1990) + A1 (1993) + A2 (1995) + A12 (1993)
- CAN/CSA C22.2 No. 601-1-M90 (1990) + S1 (1994)
- IEC 601-2-27 (1994) / EN 60601-2-27 (1994)
- IEC 601-2-30 (1995) / EN 60601-2-30 (1995)
- IEC 601-2-34 (1994) / EN 60601-2-34 (1995)
- ISO 9919 (1992) / EN865 (1996)
- ISO 9918 (1993) / EN864 (1996)
- ISO 7767: Oxygen monitors for monitoring patient breathing mixtures – Safety requirements
- ISO 11196:95+Corr. 1:97 / EN 11196:1997: Anaesthetic gas monitors
- IEC 60601-2-40:1998: Electromyographs and evoked response equipment
- AAMI EC13-1992: Cardiac Monitors, heart rate meters and alarms
- AAMI SP10-92: Electronic or automated sphygmomanometers. Note: AAMI SP10A-1996 Amendment is considered not to apply to the Cardiocap 5 since intended use is from 5 kg (11 lb.) up and the amendment gives requirements for neonatal use.

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for Datex-Ohmeda Cardiocap 5 (REV. B) and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

Mr. Joel C. Kent
Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K012837
Trade Name: Datex-Ohmeda Cardiocap 5 (REV. B) and accessories
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MLD
Dated: August 19, 2001
Received: August 23, 2001

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

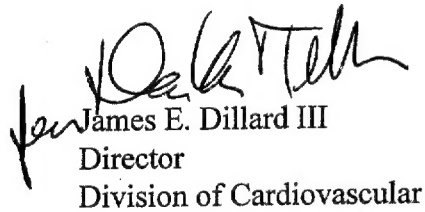
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012837

Device Name: Datex-Ohmeda Cardiocap 5 (REV. B) and accessories

Indications For Use:

The Datex-Ohmeda Cardiocap 5 (REV. B) and accessories are indicated for indoor monitoring of hemodynamic (ECG, Impedance respiration, NIBP, Temperature, SPO2 and invasive pressure) , respiratory (CO2, O2, N2O, respiration rate, anesthetic agent and agent identification), ventilatory (airway pressure, volume and flow) and relaxation status (NMT) of all hospital patients.

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Impedance Respiration measurement is indicated for patients ages 3 years and older.

Cardiocap/5 is indicated for patients weighing 5 kg (11 lb.) or more.

The monitor is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012837